Government of Ontario Green Paper

September 1989

Biotechnology in Ontario— *Growing Safely*

Ontario

GOVERNMENT OF ONTARIO GREEN PAPER

BIOTECHNOLOGY IN ONTARIO – GROWING SAFELY

September 1989

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GOVERNMENT OF ONTARIO GREEN PAPER

BIOTECHNOLOGY IN ONTARIO – GROWING SAFELY

The new opportunities provided by current developments in many areas of biotechnology are extremely important to the future prosperity of Ontario. At the same time, there is uncertainty about the consequences of the accidental or deliberate release of unnatural, living organisms into the environment.

The Government of Ontario recognizes the necessity of providing a regulatory framework that assures the protection of human health and the environment and thereby allows innovation and investment to occur in an atmosphere of safety and certainty.

Public input into the development of policy is essential since biotechnology crosses many traditional boundaries. It is a rapidly developing science in which almost all of the professional and practical skills are to be found in the private sector and in research laboratories.

It is a pleasure to acknowledge the valuable contributions of the expert multistakeholder group that assisted a seven-ministry committee in identifying many of the issues that merit public discussion. These issues are presented in this Green Paper to provide a focus for public debate and response.

On behalf of the Government of Ontario, we invite your participation. By contributing, you may assist the Government of Ontario to determine how Ontarians may benefit from new advances in biotechnology.

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Environment

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September 1989

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GOVERNMENT OF ONTARIO GREEN PAPER

BIOTECHNOLOGY IN ONTARIO – GROWING SAFELY

SECTION I

INTRODUCTION

I.1 WHY A GREEN PAPER ON BIOTECHNOLOGY?

The objective of this Green Paper is to give Ontarians an opportunity to participate in the development of regulatory policy relating to exciting new advances in biotechnology.

Traditional processes using biotechnology, such as the brewing of beer and the making of wine, are well established. New applications of biotechnology have exposed new horizons by providing alternative ways of synthesizing chemicals, of preparing novel reagents for the diagnosis and treatment of disease, of destroying wastes, of recovering minerals and of breeding plants and animals.

The Government of Ontario recognizes the potential benefits and has encouraged investment and innovation in biotechnology. But these new techniques and products may present new risks to human health and the environment. The government has undertaken public consultation to examine the issues and to develop regulatory policy that will protect human health and the environment. The Government of Ontario will use the public response to promote co–ordination with current federal initiatives in this field and to encourage the development of a truly national and comprehensive regulatory approach.

I.2 WHAT ARE THE POLICY OBJECTIVES?

The primary objective is to develop policy that assures protection of human health and the environment in a timely and sensitive manner.

The second objective is to define an appropriate regulatory framework that sets out the requirements for all biotechnological work in Ontario.

The third objective is to seek consistency with requirements in other jurisdictions so that Ontario may benefit from a national approach.

I.3 WHAT IS IN THE GREEN PAPER?

This paper describes biotechnology (Section II) and some of the opportunities that exist for commercial exploitation (Section III). It reflects on the need to identify potential risks when there is little factual information.

The current state of biotechnology in Canada and Ontario is outlined, in Sections IV and V respectively, to provide background for comment. Jurisdictional issues are described: they are especially important since there are responsibilities relating to biotechnology at both the federal and the provincial levels of government. Current approaches to legislation and control are to be found in Section VI.

Section VII identifies major issues and matters of principle that are common to all applications of biotechnology. This section is intended to stimulate response from the different perspectives of all interested parties.

As with any other technological change, there are a number of social and economic dilemmas associated with the use of biotechnology, including ethical considerations of experimentation with the basic elements of life. The implications of unethical or amoral applications of some biotechnological techniques are recognized as important issues but they are not factors in developing the regulatory framework and are not, therefore, dealt with in this Green Paper.

Finally, two possible approaches for providing a legal framework for the regulation of biotechnology are outlined in Section VIII.

I.4 WHAT IS THE PROCESS?

The Government of Ontario has initiated a process to inform the public about the nature and scope of developments in biotechnology, the existing legislation and regulatory controls and to seek public opinions on the issues that must be addressed in setting policy.

This Green Paper has been prepared to provide the background for the consultation process. It has resulted from the work of officials from seven ministries, assisted by an external advisory group (see Appendix 5) having experience in many aspects of biotechnology.

The Government of Ontario recognizes the opportunity to relate this consultation to the ongoing federal initiative to regulate biotechnology (see Section VI) and, particularly, to explore the possible co-ordination and harmonization of the requirements and sharing of information.

By developing regulatory policy through a public consultation process, the Government of Ontario can assure that full public examination and debate are afforded to the protection of human health and the natural environment. This process will facilitate the co-ordination of regulatory requirements with those of the federal government and will lead to more clearly defined and better understood legislative requirements for those operating in this field.

I.5 INVITATION TO COMMENT

The future prosperity and well-being of Ontarians will be influenced by advances in biotechnology and the manner in which they are regulated. Interested groups and individuals are invited to contribute opinions and suggestions and, thereby, to participate in policy development.

Written comments or briefs, responding to the issues identified in this paper and any other issues that may be relevant, should be sent to:

Biotechnology Green Paper Project,
Ontario Ministry of Labour,
400 University Avenue, 8th Floor,
Toronto, Ontario, M7A 1T7

not later than December 8, 1989. Requests for meetings should be made to the same address before October 20, 1989. According to demand, representatives of the inter-ministry committee are prepared to meet with interested parties during November 1989 in a number of locations across Ontario.

SECTION II

BACKGROUND

II.1 WHAT IS BIOTECHNOLOGY?

Biotechnology is the application of science and engineering to the direct or indirect use of living organisms and parts or products of organisms to provide goods and services. Traditional examples include the manufacturing of cheese and yoghurt, the making of yeast-risen bread, the brewing of beer and the selective breeding of animals and plants to improve desirable characteristics.

In the early 1970s the development of recombinant DNA technology exposed new horizons of biotechnological research. Recombinant DNA technology is the ability to splice different fragments of DNA together and then to transfer the spliced fragments and express the resulting "recombinant" molecule in the host cell. New ways of manipulating genetic material have been developed since.

The variety of scientific skills and disciplines that contribute to biotechnology are set out in Figure 1. This identifies some of the areas of developing technology and the process and enabling technologies; also, it illustrates the scope of industrial applications.*

II.2 WHY IS BIOTECHNOLOGY IMPORTANT?

With ever diminishing natural resources, use of and reliance upon applications of biotechnology appear essential if sustainable development is to be achieved in a world that is growing from five to perhaps 11 billion people in the next century. Economic and social benefits are envisaged, especially in the areas of health care, food production and waste treatment.

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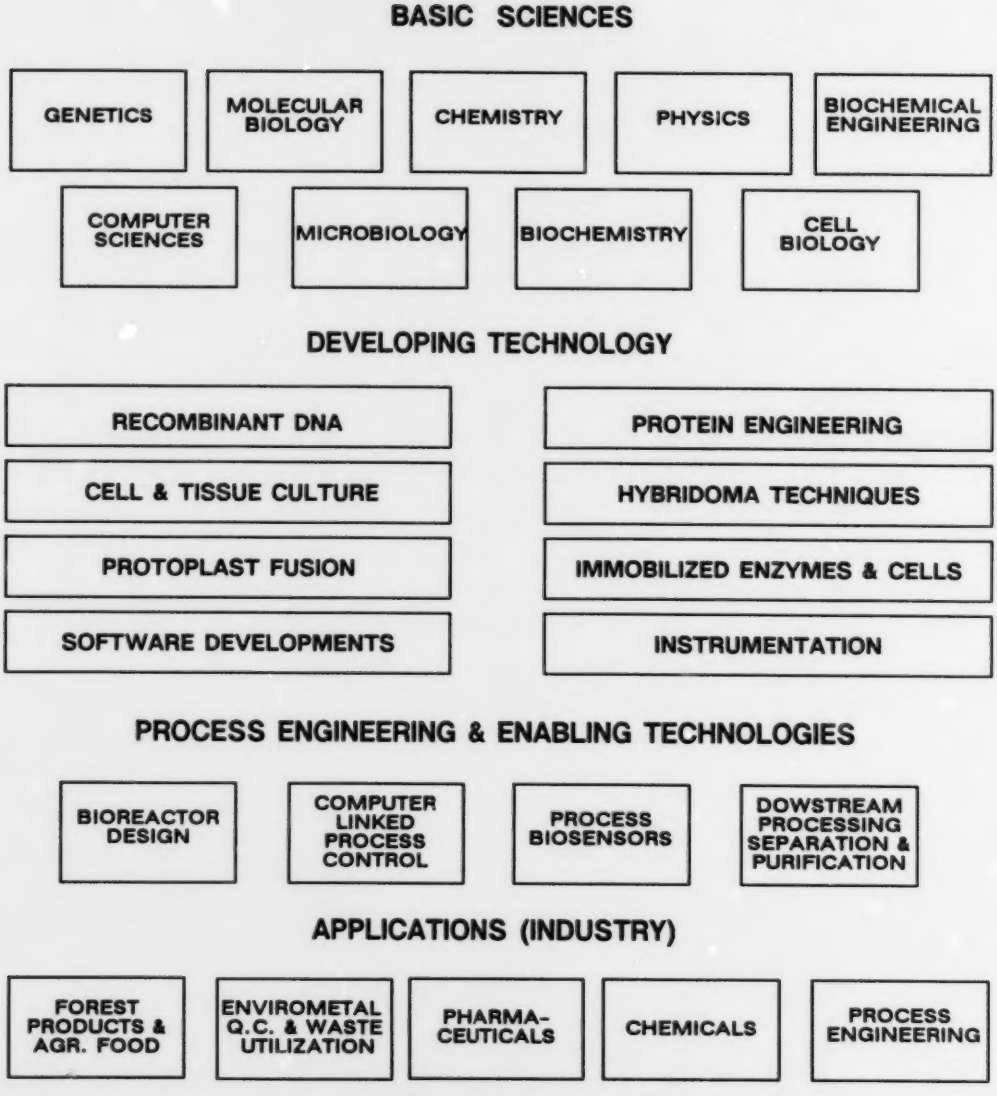
* The reader is referred to the glossary in Appendix 1 for help with the terminology.

Figure 1


BASIC SCIENCES
GENETICS
MOLECULAR BIOLOGY
CHEMISTRY
PHYSICS
BIOCHEMICAL ENGINEERING
COMPUTER SCIENCES
MICROBIOLOGY
BIOCHEMISTRY
CELL BIOLOGY
DEVELOPING TECHNOLOGY
RECOMBINANT DNA
PROTEIN ENGINEERING
CELL & TISSUE CULTURE
HYBRIDOMA TECHNIQUES
PROTOPLAST FUSION
IMMOBILIZED ENZYMES & CELLS
SOFTWARE DEVELOPMENTS
INSTRUMENTATION
PROCESS ENGINEERING & ENABLING TECHNOLOGIES
BIOREACTOR DESIGN
COMPUTER LINKED PROCESS CONTROL
PROCESS BIOSENSORS
DOWSTREAM PROCESSING SEPARATION & PURIFICATION
APPLICATIONS (INDUSTRY)
FOREST PRODUCTS & AGR. FOOD
ENVIROMETAL Q.C. & WASTE UTILIZATION
PHARMA-CEUTICALS
CHEMICALS
PROCESS ENGINEERING

SECTION III

THE GLOBAL PERSPECTIVE

III.1 WHAT ARE THE EXPECTED BENEFITS OF BIOTECHNOLOGY?

New applications of biotechnology have been heralded as a means of solving many of the world's most pressing problems.

For example, in the health care industry, by insertion of specific genes, micro-organisms can be "designed" to produce complex molecules, such as growth hormones, insulin and interferon, more efficiently and by means of simpler manufacturing processes. Also in the health care field, antibodies may be produced to facilitate diagnosis of diseases such as cancer, hepatitis and AIDS. Some also have the potential for therapeutic use. New vaccines against disease are being developed with biotechnological techniques.

Biological systems can be used for the commercial production of commodity chemicals and fuels that are otherwise derived from finite resources, such as oil. Some specialty chemicals can be produced by micro-organisms.

Selective plant and animal breeding can yield hardier and more productive strains with greater resistance to diseases or to adverse conditions such as drought or cold. These applications are of particular importance in integrated pest management schemes in forestry and agriculture, which seek to reduce dependence upon chemical pesticides.

Applications of biotechnology can be used to produce renewable biomass for sustainable energy production, to convert industrial and municipal wastes to usable sources of energy, to facilitate the recovery of oil, extract oil from tar sands and to remove sulphur from crude oil and coal.

In the field of pollution control, micro-organisms that can degrade pollutants have been isolated; other micro-organisms may be used to facilitate the recovery of by-products or the treatment of wastes. The development of enhanced micro-organisms, capable of degrading toxic wastes, offers a promising means of dealing with our widespread pollution problems.

In mining, applications of biotechnology can facilitate recovery of metals from tailings or low grade ore and destroy troublesome organic materials in metallurgical systems.

III.2 WHAT ARE THE HAZARDS AND RISKS OF BIOTECHNOLOGY?

Actual or potential hazards will vary according to the biotechnological process or product (See section VI.1) under consideration. It is quite impossible to generalize: each product or process will need to be considered on a case-by-case basis. The genetically-manipulated cow that produces a greatly increased milk yield does not pose a health hazard to humans or to the environment, whereas it would be prudent to consider a genetically-manipulated virus, such as the rabies virus, as hazardous until proven otherwise.

Because there is still some uncertainty about the actual risks, there is a need for caution. Some of the concerns expressed within member countries of the Organisation for Economic Co-operation and Development (OECD) in the early 1970s included the potential for human and ecological damage from genetic manipulation of plant and animal material and the need to seek some form of collective, protective action. Not surprisingly, the ethics of experimental work with genetic material, the implications for biological warfare and the potential for ecological disaster were issues that attracted particular attention.

Against a background of uncertainty, some research scientists voluntarily developed and accepted stringent procedures for laboratory research work, such as those set out in guidelines by the National Institutes of Health in the U.S. and the Medical Research Council (MRC) in Canada. The MRC guidelines, which have been revised several times, are accepted in many research institutes and in the private sector, even though compliance is not required by law.

While the MRC guidelines are voluntary, industry reports that the safety record in the chemical and pharmaceutical sectors, especially in the field of research with recombinant DNA, is good. It is of the conviction that the levels of risk associated with biotechnological processes are not very different from those experienced in the normal production of chemicals and pharmaceuticals. There is a risk that live bacteria or impurities might remain in the final product. Where the product is a pharmaceutical, for example, quality control is a responsibility of the Government of Canada.

Many of the biotechnological advances in the health care field appear relatively free from risks. Examples include the development of DNA probes and diagnostic kits, their laboratory use on isolated cells and the use of drugs produced by fermentation techniques using modified micro-organisms.

III.3 CURRENT KEY CONCERNS

The potential ecological impact of the deliberate or accidental release of biotechnologically derived products, including living organisms, into the open environment is an unresolved issue. Although the behaviour of the parent organisms can be predicted, minor changes in cell structure may lead to significant changes in the characteristics of the recombined organisms and uncertainty about their effects on ecosystems. Considerable current attention is being given to the development of protocols for risk assessment in this area.

In applications such as waste clean-up and mineral recovery from tailings, there is concern that modified micro-organisms may thrive beyond the waste site or the mine and have unpredictable effects on the natural environment.

Bacteria have been used to clean up oil spills and to empty oil wells of the remaining deposits that cannot be removed by pumping; however, uncontrolled use of such organisms could compromise valuable petroleum resources.

The nature and extent of the risks associated with field testing of new strains of plants and animals remain issues. In agriculture, there has been concern that herbicide-resistant strains may transfer their resistance to their weedy relatives (e.g. from canola to wild mustard), and thus create a weed that is resistant to particular herbicides.

The lack of a provincial regulatory framework and of the necessary protocols for the risk assessment applicable to biotechnological products and processes has created uncertainty, whereas a defined and stable regulatory environment is needed to encourage investment and innovation.

This Green Paper identifies some of the issues surrounding the safe development of biotechnology, to which the Government of Ontario is committed.

SECTION IV

BIOTECHNOLOGY IN CANADA

IV.1 THE SCALE AND SCOPE

In 1983 the federal government formally recognized biotechnology as a national priority for economic development based upon its potential contribution to Canadian resource and manufacturing industries. Four areas of strategic importance to Canada were identified:

- nitrogen fixation and plant strain development
- metal recovery and mineral leaching
- cellulose utilization and waste treatment
- human and animal health care.

The goals were to enhance scientific research and industrial applications, encourage skilled human resource development, increase scientific co-operation and technology transfer and foster an economic and regulatory climate conducive to commercial biotechnology investment and activities.

The strategy provided for:

- the formation of the National Biotechnology Advisory Committee to advise and to monitor progress
- the establishment of networks to establish and foster links between research institutions and users
- the formation of an interdepartmental committee to provide a forum for discussion.

Spending on research and development in biotechnology in Canada is small compared with corporate spending in the U.S. (see Table 1). Canada ranks ninth in relation to world-wide public spending (see Table 2). In 1985 research and development spending in Canada was spread over a number of sectors (see Figure 2). Data reflecting the scale of the biotechnology industry in Canada in 1986 are to be found in Table 3.

Table 1

BIOTECHNOLOGY R&D EXPENDITURE: A Comparison Of U.S. Corporation And Total Canadian Spending

Company	Biotechnology R&D 1985 (Cdn.$000s)
Monsanto	$266,500
Merck	245,520
Dupont	198,000
Canadian Federal Government*	104,617
Genentech	85,661
Cetus	79,200
All Canadian Industry	65,593
Genetics Institute	25,596

*Includes capital expenditures.
Source: Ministry of State for Science & Technology. Annual Reports; Canada Consulting Group analysis

Table 2

PUBLIC SECTOR FUNDING OF BIOTECHNOLOGY WORLDWIDE 1985–86

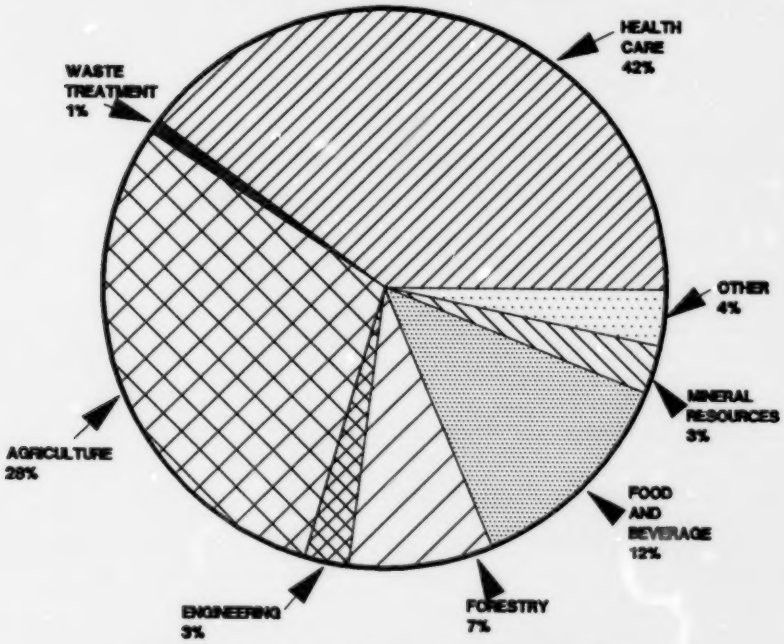
Country	Annual Expenditure $ Millions
United States	$2,835
Japan	412
France	335
West Germany	327
United Kingdom,	267
Sweden	150
Denmark	134
Switzerland	120
Canada	79
Italy	69
Belgium	49

Source: European Biotechnology News/M.O.S.S.T.

Figure 2

CANADIAN BIOTECHNOLOGY ORGANIZATION
R&D EXPENDITURES PER SECTOR, 1985 *

Source: Ministry of State for Science and Technology, 1986
(now Industry Science & Technology Canada)



Total Reported Expenditures: $65,593,000

* Based upon the 71% of the organizations that reported R&D expenditures

Table 3
THE BIOTECHNOLOGY INDUSTRY IN CANADA

	# of Firms	% of Total	Reported R&D Expenditures* ($000)	% of Total	Average R&D Per Firm ($000)	Reported Scientific Personnel**	% of Total
Health Care***	31	29%	$27,300	42%	$900	368	41%
Food Processing	22	20%	8,000	12%	400	119	13%
Animal & Plant Agriculture	13	12%	18,400	28%	1,400	211	24%
Forestry	11	10%	4,500	7%	400	49	6%
Engineering	10	9%	2,000	3%	200	26	3%
Waste Treatment	8	7%	600	1%	80	23	2%
Mineral Processing	5	4%	200	3%	40	21	2%
Other	10	9%	2,900	4%	290	76	9%
Total	100	100%	$65,593	100%	$596	893	100%

*R&D expenditures were reported by 78 firms.
**Scientific personnel were reported by 90 firms.
***Includes expenditures on clinical trials.
Source: Ministry of State for Science & Technology. 1986.

Because of the enormous variety of applications, growing numbers of research centres in universities, hospitals and private corporations are engaging in biotechnological research and development in Canada.

In a 1986 survey 110 Canadian companies indicated that they were involved in biotechnological research. The 1988 Canadian Biotechnology Industry Sourcebook listed 218 respondents involved in this type of research and development, a doubling over two years. Many of the private companies derive their incomes from research grants and contracts and are very small. In international terms, Canada is a minor participant in biotechnology research.

SECTION V

ONTARIO

V.1 BIOTECHNOLOGY IN ONTARIO

Ontario has encouraged the development of the biotechnology industry, through both public investment and the private sector. Table 4 lists the largest biotechnology laboratories in Ontario. In 1982 the Ontario Development Corporation made a large commitment of funds to Allelix, now one of Canada's largest biotechnology companies. The Ontario government took a 20 per cent equity interest in the firm and committed a further capital loan of $15 million, together with $18 million over ten years, for operations.

Table 4

ONTARIO'S LARGEST BIOTECHNOLOGY LABORATORIES

	R&D Expenditures (1985-86) $000s	Number of Scientific Staff In-House
Allelix	$15,000	140
Connaught Laboratories	3,300	20
Eli Lilly Canada	2,481	22
Syntex	2,000	NA
Cangene	1,750	18
Labatt Brewing	1,600	35
Denison Mines	1,600	1
Total	$27,731	236
Remaining 39 Firms	$8,561	176

Source: Ministry of State for Science & Technology. 1986.

A great deal of Canada's university and government biotechnology research is done in Ontario. Ontario also contains Canada's largest industrial interest in biotechnology (45 per cent), but this involvement is still very small in international terms. Over 50 per cent of the Ontario companies have fewer than 50 employees, and only five of the 84 companies surveyed have a biotechnology department of over 30 people. One-quarter of the Ontario companies have fewer than 10 employees.

One-third of the biotechnology industry in Ontario is devoted to health care. Agriculture is the next largest component, with food and beverages and waste treatment close behind. Ontario's spectrum of industrial applications includes:

health care	–	development of vaccines, immunodiagnostic kits, neonatal screening, diagnosis and treatment of cancer products for human tissue repair, growth hormones, anti-inflammatory drugs, therapeutic agents for control of the central nervous system
agriculture	–	pest-resistant plants, veterinary medicines, animal breeding, nitrogen fixation in the soil to reduce the need for fertilizers
forestry	–	biological control of insects and diseases, development of fast-growing or pest-resistant trees, gene pool preservation and new breeding and propagating techniques, biofertilization with mycorrhiza and biological bleaching techniques in paper and pulp production and new uses for by-products
waste-treatment	–	microbes for decomposition of sewage waste, and cleaning oil spills and decontaminating soil
food/cheese beverage	–	use for improved production of wine, beer, corn sweeteners
chemical/energy	–	new energy sources, production of methanol from waste products
mineral leaching	–	use of microbes to remove minerals from ores, to reduce the hazard of methane gas in mines and reduce acid mine drainage problems
aquaculture	–	development of new and larger fish and fish vaccines and uses of fish residue and seaweed extracts; algae control.

SECTION VI

LEGISLATION AND CONTROL

VI.1 BACKGROUND

An outline of the approaches to legislative control in some other countries is included in Appendix 4. In Canada, jurisdiction over biotechnology, as with many other issues affecting public and environmental health and safety, is a shared responsibility of the federal and provincial governments. It is necessary to consider the approaches of the two levels of government to determine the opportunities for complete coverage as well as for the harmonization of legislation and controls.

VI.1A Regulatory Controls Proposed by the Government of Canada

"Biotech – A User's Guide", recently published, summarizes the mandates of three federal departments, Agriculture Canada, Environment Canada and Health and Welfare Canada, to regulate biotechnology. It is stated in the guide that current legislation is generally adequate to accommodate biotechnology products but that specific requirements and guidelines are under development in preparation for future need. A summary chart from the guide is to be found in Appendix 3. The guide should be consulted for further detail; it will be supplemented as other federal agencies examine their statutes.

It should be noted that most of the controls proposed by the Government of Canada relate to products rather than to the safety of biotechnological processes, many of which fall under provincial jurisdiction. Responsibility for the health and safety of workers, waste disposal and the safe use of pesticides, for example, rests with the Government of Ontario.

VI.IB Responsibilities and Authority

The jurisdictional authorities are complex and overlap to some extent. The references cited in the bibliography provide greater detail.

To illustrate, consider a new substance for use in pollution degradation, waste disposal, mineral leaching, chemical production or lignin degradation. Notification of importation or manufacture of a new substance is required under the *Canadian Environmental Protection Act*. The applicant will be required to provide information that will be assessed by Environment Canada and Health and

Welfare Canada before importation or manufacture. This assessment, which, for commercial manufacture, would include review of the design and safety of the process, does not include consideration of worker health and safety or the disposal of waste following production since these matters are controlled by the provinces. However, the information required and assessed by federal departments will be similar to that required for assessments related to provincial responsibilities. If replication of effort is to be avoided, a mechanism will be needed for sharing information between the two levels of government.

VI.2 CANADIAN APPROACH TO MANDATORY CONTROLS AND VOLUNTARY RESTRAINTS

VI.2A Mandatory Controls

In keeping with OECD recommendations and the approach used in many other countries, the Government of Canada intends to control the products of biotechnology through the use of existing legislation. Specific requirements are being developed under existing product oriented statutes (see Appendix 2) by the Departments of Agriculture, Environment and Health and Welfare. Proposals to disperse products of biotechnology deliberately into the environment will be considered on a case-by-case basis.

Some products of biotechnology are subject to the requirements of the recently enacted *Canadian Environmental Protection Act* (CEPA); exceptions include products for use as pesticides, which are subject to the *Pest Control Products Act*. Provision of prescribed information to permit assessment of health and environmental effects of new products not similarly assessed under other legislation will be required when the relevant section of CEPA is proclaimed after the preparation of the Domestic Substances List.

VI.2B Voluntary Restraints

Two approaches to voluntary restraint are in current use: adherence to guidelines and the establishment of biosafety committees.

An *ad hoc* committee, convened by the Medical Research Council of Canada (MRC) in 1977, developed guidelines for handling DNA preparations, human and animal viruses and cells in laboratories. Compliance with the guidelines was a condition for funding of research projects by the MRC. The guidelines have been revised and expanded recently to include other organisms and have become widely accepted in research laboratories.

Biosafety committees have been established in a number of large research institutes and some corporations in Canada. The responsibilities of these committees include inspection of facilities, monitoring of operations and procedures and operator training. Many such committees have developed biosafety manuals based on the MRC guidelines; these manuals have become the texts for monitoring and training procedures.

Biosafety committees have evolved to the point where some are regarded as a potential local resource that might provide advice to small units or inexperienced individuals undertaking biotechnological work. A federal interdepartmental subgroup on safety and regulation of biotechnology is to explore the possibility of establishing minimum standards that will ensure the competence of biosafety committees.

Guidelines for other stages of production and testing, including Good Industrial Large-Scale Practice (GILSP), are being developed by OECD member countries, including Canada.

VI.3 THE APPROACH TO CONTROLS IN ONTARIO

Several ministries of the Government of Ontario administer statutes and regulations applicable to the control of biotechnology. The responsibilities of the ministries are summarized in this section and the recognized potential gaps in the regulatory framework are identified. A preliminary assessment of legislation was made for Environment Canada by Henley in 1987, but it seems likely that additional gaps will become apparent as actual case-by-case assessments are made.

The Ministry of the Environment administers the *Environmental Protection Act*, which states that no person shall deposit in, add to, emit or discharge into, the environment any contaminant. The *Ontario Water Resources Act* contains a similar prohibition against discharges to water. Prior approval is needed with respect to proposed facilities that emit to the air or water or that are intended for waste disposal. These Acts, however (with some exceptions), do not currently regulate products intended for deliberate release into the environment.

The Ministry of the Environment also administers the *Pesticides Act*, which regulates the sale, use, transport and disposal of all pesticide products in Ontario. This legislation complements the federal pesticide registration process

under the *Pest Control Products Act*. Definitions under the provincial *Pesticides Act* include all biological agents and biotechnology products used for pest control purposes; however, appropriate hazard assessment protocols and guidelines need to be developed.

The Ministry of Labour has jurisdiction in respect of worker health and safety. Under the *Occupational Health and Safety Act* (OHSA), the duty of the employer to inform, instruct and supervise workers for the protection of health and safety applies equally to hazards posed by biotechnological processes and products and to those posed by other manufacturing processes and products. The requirement for an employer to notify the ministry of the manufacture, distribution or supply of a new biological or chemical agent applies also. The OHSA, however, does not apply to farming operations.

Other important legislation that is relevant but not directed at controlling new types of biotechnological development includes the *Health Protection and Promotion Act*, administered by the Ministry of Health. This contains the general duty of the medical officer of health to prevent, eliminate or decrease the effects of health hazards within the area of the health unit.

The Ministry of Agriculture and Food administers a number of relevant statutes: the *Animals for Research Act*, the *Artificial Insemination Act*, the *Plant Diseases Act* and the *Milk Act*. It has also a number of policies and programs that relate to biotechnology products. For example, under Food System 2002, the use of microbial pesticides will be essential if the goal of a 50 per cent reduction in chemical pesticides during the next 15 years is to be achieved.

The Ministry of Natural Resources has no statutory authority over, but it has a major interest in, biological pest control and the development of biological techniques for tree propagation and biofertilization.

As biotechnological products and processes move out of the research laboratory into our daily lives, the role of mandatory controls, voluntary restraints and optional compliance with codes of good practice must be a matter for public review and debate.

SECTION VII

ISSUES OF CONCERN TO ONTARIO

VII.1 MAJOR ISSUES

There can be little doubt about the importance of the industrial development of biotechnology for sustainable economic growth over the next few decades. Public awareness, perceptions and understanding of the complexities of biotechnological techniques and products will be important factors in determining the rate of development of the industry. Achieving and maintaining public confidence in the procedures adopted to safeguard human health and the natural environment are critically important. Another factor is the desire of potential investors and innovators to operate in a defined regulatory environment.

This section identifies major issues and matters of principle that are common to all applications of biotechnology. It is important that they be addressed from different perspectives in order to identify the common ground upon which to build a co-ordinated regulatory framework.

1 HOW CAN THE PREMISES OR SITES WHERE PEOPLE ARE ACTIVELY ENGAGED IN BIOTECHNOLOGY BE IDENTIFIED?

The potential hazards of biotechnological work do not necessarily relate to the scale of the operation. Small operations may be more hazardous because of inadequate equipment, containment, or training of the operator. Locations and premises may be hard to identify when the scale is small.

Option: require notification to a government department of all work within a broad definition of biotechnology.

Comment: this would allow a registry to be maintained that would facilitate follow-up should a hazard become evident only after a latent period.

2 ARE MANDATORY CONTROLS FOR ALL TYPES OF BIOTECHNOLOGY NECESSARY TO SAFEGUARD HUMAN HEALTH AND THE NATURAL ENVIRONMENT?

As scientists have become more familiar with biotechnology, there is a growing impression, and some evidence, that some biotechnological techniques and processes are more hazardous than others.

Option 1: impose standards by legislation for those activities deemed potentially hazardous.

Comment: mandatory conditions should apply not only when there is actual evidence of harm, but when there is expert assessment that a hazard may exist.

Option 2: impose standards by legislation for all biotechnological work.

Comment: this would seem to be unnecessary where, for example, a new plant or animal strain has been assessed as being of minimal concern.

3 IS THERE A PLACE FOR ADHERENCE TO NON-LEGISLATED GUIDELINES OR CODES OF GOOD PRACTICE?

The experience of adherence to the MRC Guidelines by laboratory research workers has been good, though influenced by conditions linked to grants. Some companies are known to have voluntarily accepted the MRC Guidelines, with compliance being monitored by a biosafety committee.

Option 1: extend the use of guidelines to some or all workers involved in prescribed applications of biotechnology.

Comment: this provides the opportunity for "the bad actor" to take risks and to expose others to potential harm, but a program of voluntary compliance could be restricted to specific types of work where risks are considered minimal. A voluntary program without an economic incentive might be less effective.

Option 2: extend the use of guidelines but ensure that practices are monitored by, for example, a biosafety committee or a workplace joint health and safety committee.

Comment: monitoring would provide some reassurance, but the sanctions that could be applied may be limited.

4 WHAT IS THE ROLE OF BIOSAFETY COMMITTEES IN AREAS OF PROVINCIAL JURISDICTION?

Biosafety committees have evolved in laboratories where the MRC Guidelines have been applied. It has been suggested that an existing biosafety committee could provide advice to others upon request, e.g. small operators. There are questions about membership, roles and responsibilities of such committees and how they would relate to the joint health and safety

committees or worker representatives required under OHSA, particularly if an accreditation scheme is to be developed.

Option 1: the functions of biosafety committees could be assigned to workplace health and safety committees, where they exist.

Comment: special training of committee members may be required; the relevance of a federal accreditation scheme (if developed) would need to be determined.

Option 2: separate biosafety committees could function in an advisory capacity to a workplace joint health and safety committee.

Comment: this may be an option only in comparatively large establishments; many biotechnology operations are on a small scale.

5 HOW SHOULD THE SAFETY OF BIOTECHNOLOGICAL PROCESSES BE ASSESSED?

Control over most workplaces, emissions and wastes rests with the provinces; hence the need for consideration of the safety of these processes and activities. It is inevitable that information relating to potential risks will be inadequate. What criteria should therefore be applied, and by whom, to determine what operating conditions should apply? Should there be provision for defining the criteria for assessing different levels of risk such as between the use of recombinant organisms and pathogenic viruses?

Option 1: establish general criteria.

Comment: interpretation would be a matter for the employer, the workplace health and safety committee where required under the *Occupational Health and Safety Act* and the government inspector. Criteria might be established with multistakeholder assistance.

Option 2: identify and specify only those categories of potentially hazardous biotechnological work that would require assessment.

Comment: this would prevent delays in the use of benign procedures or processes.

6 HOW SHOULD THE SAFETY OF BIOTECHNOLOGY PRODUCTS BE ASSESSED?

When the Government of Canada has been notified of a biotechnology product and some assessment of its properties has been carried out, what

procedure(s) should be followed by Ontario with respect to manufacture, use or release to the environment?

Option 1: accept the outcome of the federal assessment without further review.

Comment: information about the product may be insufficient to allow decisions relating to matters under provincial jurisdiction, e.g. waste disposal.

Option 2: seek access to the information and data upon which the federal decision was based and determine the need for control requirements relating to worker protection, emissions, waste disposal and ecological impact.

Comment: access to information disclosed to the Government of Canada and to the opinions of the federal assessors would simplify the procedures and reduce the time needed for Ontario to define requirements relating to use, emission control and disposal of waste and to deal with other matters falling under provincial jurisdiction. One or more federal-provincial agreements would be needed.

Option 3: Ontario could set the criteria, perhaps with multistakeholder assistance; the criteria would be applied by the appropriate ministry.

Comment: the province could act independently, but would at least partially replicate data requirements and some of the assessment.

Option 4: Ontario should selectively review federal information for products deemed more hazardous to the environment.

Comment: As for Option 2.

7 HOW SHOULD ONTARIO DEFINE BIOTECHNOLOGY?

There are almost as many definitions of biotechnology as there are applications of it. The issue is whether or not to adopt a broad definition.

Option 1: adopt the federal definition contained in the *Canadian Environmental Protection Act*.

Comment: this is an all-inclusive, if somewhat cumbersome, definition. Rationalization and harmonization of legislated requirements between the Governments of Ontario and Canada would be facilitated by the use of a common definition.

Option 2: create a new definition.

Comment: this may prevent the effective co-ordination of requirements by the federal and provincial governments.

8 HOW MAY REGULATORS RESPOND TO THE NEEDS OF INVESTORS AND INNOVATORS?

Investors and innovators have indicated their need for reasonable regulations and a clearly defined regulatory environment within which they will operate. In addition, they seek consistency of Ontario's regulations with those of other Canadian jurisdictions and those of our trading partners.

Option 1: regulatory control could be geared to the level of risk associated with the particular biotechnological process or product.

Comment: this approach would ensure that the protection of human health and the natural environment would determine the level of regulatory control.

Option 2: a single standard of regulatory control could be applied to all biotechnological work.

Comment: a single standard would have the disadvantage of being inappropriate to the protection of human health and the natural environment when the risks are either very low or very high.

Option 3: make efforts to ensure that Ontario regulations are comparable to those in other jurisdictions.

Comment: the promotion and development of a nationally consistent set of regulations that protect human health and the natural environment will provide a level of certainty for the investor community.

Option 4: prepare Ontario regulations without consideration of those in other jurisdictions.

Comment: while providing Ontario with more autonomy, this will not respond to investors' need for consistency across Canada for their corporate development.

VII.2 OTHER ISSUES FOR DISCUSSION

There are other questions and matters of interest on which the reader is invited to comment. The following list is not necessarily comprehensive:

VII.2A In the Workplace

1 It has been suggested that the larger the industrial premises the greater the risks. Is there any evidence to support this contention?

2 Are existing waste handling procedures safe and adequate to deal with biotechnological products in the workplace?

3 Is there a need to find a means of defining the extent of workplace contamination by biotechnological products?

4 Are safeguards necessary for those who work on agricultural operations since they are currently excluded from the provisions of the *Occupational Health and Safety Act*?

5 Is there a need for special orientation and training of workers in institutions involved in biotechnology?

6 Should a joint health and safety committee be required in any workplace where biotechnological work is undertaken and where there is more than one worker?

7 What safeguards may be needed to protect the public from the biotechnology activities of hobbyists?

8 University research and development is subject to the provisions of the *Canadian Environmental Protection Act*. Is there a need for additional specific regulations, for example, under the *Occupational Health and Safety Act*?

VII.2B Environmental Releases, Discharges, Emissions and Waste Disposal

1 Should there be shared responsibility with the Government of Canada for the assessment and legislative controls applicable to the deliberate dispersion of biotechnological products into the environment, including experimental field trials?

2 The *Environmental Protection Act* and the *Ontario Water Resources Act* are the current Ontario statutes used for controlling emissions, discharges, wastes and spills. Should these Acts be modified to allow for approval and regulation of biotechnological products, other than pesticides, released into the environment?

3 Are the existing procedures for approving pesticides for sale and use in Ontario suitable for products of biotechnology or should separate protocols be established?

4 Can and should the regulatory controls applicable to chemical wastes also be applied to biotechnology wastes?

5 Should specific procedures or criteria be established for the satisfactory clean-up of a spill or a contaminated site?

VII.2C Communication, Public Education and Participation

Effective multistakeholder participation in a process intended to assist policy development depends upon raising awareness and increasing understanding of the parties in relation to the techniques, the potential hazards and the issues associated with them.

1 What measures, general or special, should be taken by organizations, institutions and the Government of Ontario to assist the public in becoming better informed about biotechnology?

2 How may citizens willing to assist in the decision-making process be identified?

3 Are sufficient resources being devoted to education and training in biotechnology? Are there sufficient skilled scientists and technicians to prepare and enforce regulations?

SECTION VIII

POSSIBLE LEGAL FRAMEWORKS FOR ONTARIO

There are several possible structures for establishing a legislative framework for the regulation of biotechnology. In any approach adopted, the Government of Ontario would ensure the maximum possible co-ordination of regulatory requirements, provincial and federal. For discussion purposes, two possible approaches are outlined. Comments on these and other suggestions are invited.

Approach 1

This involves development of a *new Biotechnology Act* that would provide for centralized receipt of notification of all biotechnological work and a "single window" referral mechanism to provincial control requirements. This agency would develop and administer the provincial notification system and would facilitate referral to the appropriate ministry or ministries for detailed assessment. Elements of this approach include:

1 A *Biotechnology Act* establishing one primary agency for the notification and referral of all biotechnological initiatives falling within provincial jurisdiction.

2 All private and public sector parties engaged in biotechnological work would be required to notify the central agency, in accordance with the standardized information requirements.

3 The central agency would assess the notifications to prevent federal-provincial jurisdictional overlap in responsibility and to provide the notification package to the appropriate ministry or ministries for specific regulatory action.

4 Existing statutes and regulations would be used to control biotechnology. This would include the *Environmental Protection Act*, the *Pesticides Act* and the *Occupational Health and Safety Act*, among others. If necessary, these would be amended to ensure applicability to biotechnology (see Section VI.3 for a description of existing provincial legislation). Where necessary, new regulations dealing specifically with biotechnology would be drafted under existing statutes.

5 Individual ministries would deal directly with the applicant, and the central agency would be kept apprised of the applicable control requirements.

The advantages of this approach include:

1 It would provide a single window for interested parties to interact with the government during the notification and referral stage and for general information on applicable laws and possible business incentives.

2 It would avoid duplication of notification and assessments by directing all notification to the appropriate ministry or ministries for initial assessment and by maintaining a link with the federal government.

Disadvantage:

1 Some additional time and resources would be required to introduce and implement a new act and to establish the new agency.

Approach 2

This would also build on the existing legislation that provides for the control of chemical substances. It would require that some existing legislation be amended to control biotechnology. A non-legislated mechanism would be established to co-ordinate biotechnological regulatory activities between the involved ministries.

1 Existing statutes and regulations would be used to control biotechnology. This would include the *Environmental Protection Act*, the *Pesticides Act* and the *Occupational Health and Safety Act*, among others. If necessary, these would be amended to ensure applicability to biotechnology (see Section VI.3 for a description of existing provincial legislation). Where necessary, new regulations dealing specifically with biotechnology would be drafted under existing statutes.

2 All private and public sector parties engaged in biotechnological work would be required to notify the required ministry or ministries.

3 The individual ministry or ministries notified would consult with all Ontario ministries involved with biotechnology to ensure that provincial requirements are met.

4 Individual ministries would deal directly with the applicant.

Advantages:

1 This approach would take less time to develop and implement.

2 Government would be responding to industry and public requests for a stable policy and regulatory environment.

Disadvantage:

1 Since the notification requirements would be spread across several statutes and provincial ministries, this approach might be less effective in ensuring that regulatory requirements are administered in a consistent manner.

SECTION IX

CONCLUSION

This paper outlines the need for a regulatory environment for biotechnology that will ensure the protection of human health and the environment. It also describes the nature of biotechnology and the benefits to be derived from it. A number of issues relating to the adequate regulation of biotechnology are raised to invite comment. Your comments will help to ensure that all points of view are considered in this significant field of regulatory development.

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APPENDIX 1

GLOSSARY

CELL FUSION	The fusion of two different cells (animal cells, protoplasts from plants or bacteria) to form a single hybrid cell containing genetic material and cytoplasm from both parents.
CLONING	The isolation and replication of DNA fragments.
CONTAINMENT	*Biological* – the development and use, for the purpose of diminishing or eliminating the possibility of their survival and/or transmission, genetically altered bacteria, bacterial viruses and plasmids that are unable to complete essential functions (e.g. growth, DNA replication, DNA transfer, infection and/or propagation), except under specific conditions. *Physical* – the use of laboratory design and practice (e.g. limited access, safety cabinets, aerosol control, protective clothing, pipetting aids) for the purpose of reducing the likelihood of personnel infection and/or the spread of organisms or genetic material.
DNA	Deoxyribonucleic acid; polymer composed of deoxyribonucleotide units; genetic material of most organisms.
FERMENTATION	Descriptive of processes in which cells or other micro–organisms are cultured in a container in a solid or liquid medium for experimental or commercial processes. The term is applied to both aerobic (requiring oxygen) and anaerobic (not requiring oxygen) processes.
FIELD TRIAL	Any planned application outside of contained facilities during product development, including pre–commercial testing.
GENE	The basic unit of heredity; a segment of DNA comprising an ordered sequence of nucleotide bases.
GENE TRANSFER	The artificial introduction of foreign genes into recipient cells or the natural movement of genetic information between organisms in the environment.
GENETIC ENGINEERING	Production of new genetic combinations not known to occur naturally and generated by techniques that are artificial mechanisms not known to occur in nature.

HYBRIDOMA	A hybrid cell produced by fusion of an antibodyproducing tumour cell and a plasma cell. A hybridoma clone produces one specific antibody of the parent plasma cell (monoclonal antibody).
INDIGENOUS	Naturally occurring in an ecosystem.
MICROCOSM	Enclosed micro-environment (such as a greenhouse) that simulates the characteristics of a real macro-environment.
NITROGEN FIXING BACTERIA	Bacteria capable of reducing atmospheric nitrogen gas to ammonia.
NON-INDIGENOUS	Organisms not naturally occurring in an ecosystem.
PARENT ORGANISM	A donor of genetic material during genetic engineering.
PATHOGENIC	Producing disease in living organisms.
PLASMIDS	A piece of genetic material that can be transferred from one cell to another.
PROTOPLAST TECHNIQUE	A technique used to produce hybrid organisms in which protoplasts derived from two different (plant) sources are fused to produce a single cell, which may then be induced to form a new cell wall and, ultimately, new plantlets.
RECIPIENT ORGANISM	Organism that receives the new genetic material.
RECOMBINANT DNA (rDNA)	Hybrid DNA sequences, from the same or different organisms, assembled *in vitro* in a novel configuration. Such recombinant molecules can be replicated in a living cell.
SEQUENCING	Determining the specific sequence of constituents of DNA and ribonucleic acid (RNA).
VECTOR	Vehicle by which foreign DNA is transferred from one cell to another, e.g. viruses or plasmids.

APPENDIX 2

FEDERAL LEGISLATION

AGRICULTURE CANADA

The *Animal Disease and Protection Act* regulates veterinary biologics, animal pathogens, animal products and by-products.

The *Feeds Act* regulates livestock feeds and feed ingredients.

The *Fertilizers Act* regulates fertilizers and supplements.

The *Pest Control Products Act* regulates all pest control products, whether for control of plant or other pests and including those that are genetically engineered.

The *Plant Quarantine Act* relates to plant pests.

The *Seeds Act* regulates new varieties or forms of seeds.

NATIONAL HEALTH AND WELFARE

The *Food and Drugs Act* regulates all human and veterinary drugs, cosmetics, food, food additives, food contaminants, medical devices and radiopharmaceuticals. It covers all pharmaceuticals produced by recombinant DNA technology (Schedule D).

The *Hazardous Products Act* regulates hazardous consumer products. Consumer and Corporate Affairs Canada administers the Act and is advised by National Health and Welfare with respect to the evaluation of health effects.

National Health and Welfare provides advice to Agriculture Canada on health effects of pesticides before and after registration under the *Pest Control Products Act*.

ENVIRONMENT CANADA AND NATIONAL HEALTH AND WELFARE

Under the *Canadian Environmental Protection Act* (CEPA), the two departments jointly regulate all toxic substances not controlled under other statutes. Information on substances new to Canada is to be provided before manufacture or importation for assessment of toxicity and potential health and environmental

effects. CEPA is based on the concept of requiring environmental management of a product throughout the life cycle, from research to final disposal.

APPENDIX 3

PRODUCT GUIDE

Biotechnology Products/Organisms	Act	Contact	Address	Guide Section
Animal pathogens/veterinary biologics; animal products and byproducts				
– veterinary biologics, including vaccines, antisera, diagnostic reagents – imported/indigenous animal pathogens or materials of animal origin	*Animal Disease and Protection Act and Regulations*	Veterinary Biologics Animal Health Division Health of Animals Directorate Agriculture Canada	801 Fallowfield Road Nepean, Ontario K2H 8P9 (613) 998–9320	1.1
Drugs and cosmetics				
– hormones and cell growth factors – drugs produced through recombinant DNA procedures – blood products such as human serum albumin, antihemophilic factor, thrombolytic and fibrinolytic enzymes – vaccines – monoclonal antibodies – allergenic extracts	*Food and Drugs Act and Regulations*	Drug Regulatory Affairs Division Drugs Directorate Health and Welfare Canada	Health Protection Building Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957–0372	3.3
– radiopharmaceuticals		Legislative and Regulatory Processes Environmental Health Directorate Health and Welfare Canada	Environmental Health Centre Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957–3142	3.3
Feeds and feed additives				
– Livestock feeds (e.g. yeasts, microbes, enzymes, fermentation products, single cell (biomass) protein)	*Feeds Act and Regulations*	Feed Section Feed and Fertilizer Division Plant Health Directorate Agriculture Canada	K.W. Neatby Building 960 Carling Avenue Ottawa, Ontario K1A 0C6 (613) 995–7900	1.2

PRODUCT GUIDE

Biotechnology Products/Organisms	Act	Contact	Address	Guide Section
Fertilizers/supplements				
– capable of producing and/or providing nutrients to plants – improving availability of plant nutrients – improving the physical condition of the soil – promoting plant growth	*Fertilizers Act and Regulations*	Fertilizer Section Feed and Fertilizer Division Plant Health Directorate Agriculture Canada	K.W. Neatby Building 960 Carling Avenue Ottawa, Ontario K1A 0C6 (613) 995–7900	1.3
Foods and food additives				
– food microorganisms – food enzymes – single cell proteins – fatty acids – oils	*Food and Drugs Act and Regulations*	Food Regulatory Affairs Division Food Directorate Health and Welfare Canada	Room 200 Health Protection Bldg. Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957–1748	3.3
Medical devices				
– *in vitro* diagnostic kits	*Food and Drugs Act and Regulations*	Legislative and Regulatory Processes Environmental Health Directorate Health and Welfare Canada	Environmental Health Centre Tunneys's Pasture Ottawa, Ontario K1A 0L2 (613) 957–3142	3.3
Pest control agents				
– naturally occurring and genetically engineered organisms; their parts and products that have pesticidal claims	*Pest Control Products Act and Regulations*	**Notification:** Pesticides Directorate Agriculture Canada	2nd Floor, SBI Building 2323 Riverside Drive Ottawa, Ontario K1A 0C6 (613) 993–4544	1.4
		Health: Legislative and Regulatory Processes Environmental Health Directorate Health and Welfare Canada	Room 128 Environmental Health Centre Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957–3142	3.5

PRODUCT GUIDE

Biotechnology Products/Organisms	Act	Contact	Address	Guide Section
Pest control agents (cont.)				
	Food and Drugs Act and Regulations	Food Regulatory Affairs Division Food Directorate Health and Welfare Canada	Room 200 Health Protection Building Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957–1748	3.3
Plant pests				
– products that are, or are likely to be, plant pests	*Plant Quarantine Act and Regulations*	Plant Protection Division Plant Health Directorate Agriculture Canada	K.W. Neatby Building 960 Carling Avenue Ottawa, Ontario K1A 0C6 (613) 995–7900	1.5
Plants/seeds				
– new varieties of plants/seeds produced by biotechnology	*Seeds Act and Regulations*	Seed Division Plant Health Directorate Agriculture Canada	K.W. Neatby Building 960 Carling Avenue Ottawa, Ontario K1A 0C6 (613) 995–7900	1.6
Products not covered above				
Consumer products				
products that are: – poisonous – toxic – inflammable – explosive – corrosive	*Hazardous Products Act and Regulations*	**Notification:** Product Safety Branch Bureau of Consumer Affairs Consumer & Corporate Affairs Canada	Place du Portage Phase 1 50 Victoria St. Hull, Quebec K1A 0C9 (819) 997–1194	3.4
		Health: Legislative and Regulatory Processes Environmental Health Directorate Health and Welfare Canada	Environmental Health Centre Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957–3142	

PRODUCT GUIDE

Biotechnology Products/Organisms	Act	Contact	Address	Guide Section
Products not covered above (cont.)				
Chemical products				
– enzymes, complex lipids, aromatic compounds polysaccharide biopolymers, and other chemicals produced by biotechnology processes	*Canadian Environmental Protection Act and Regulations*	**Notification:** Commercial Chemicals Branch Environment Canada	Place Vincent Massey 351 St. Joseph Blvd. Hull, Quebec Mail: Ottawa, Ontario K1A 0H3 (819) 994–3236	2.1
		Health: Legislative and Regulatory Processes Environmental Health Directorate Health and Welfare Canada	Environmental Health Centre Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957–3142	3.1
Other products used for:				
– pollution control – mineral leaching – chemical residue destruction – waste disposal – novel uses not covered by other acts	*Canadian Environmental Protection Act and Regulations*	**Notification:** Biotechnology Centre Commercial Chemicals Branch Environment Canada	Place Vincent Massey 351 St. Joseph Blvd. Hull, Quebec Mail: Ottawa, Ontario K1A 0H3 (819) 994–3236	2.1
		Health: Legislative and Regulatory Processes Environmental Health Directorate Health and Welfare Canada	Environmental Health Centre Tunney's Pasture Ottawa, Ontario K1A 0L2 (613) 957–3142	3.1

The "Products Guide" is reprinted from *Bio-Tech A User's Guide*, published by Industry, Science and Technology Canada.

APPENDIX 4

CONTROL STRATEGIES IN SOME OTHER COUNTRIES*

I GUIDANCE FOR MEMBER COUNTRIES OF THE ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

In its report "Recombinant DNA Safety Considerations", published in 1986, the OECD reviewed the applications of recombinant DNA techniques and the safety considerations associated with:

1 recombinant DNA (rDNA) organisms
2 large-scale industrial applications of rDNA techniques
3 environmental and agricultural applications.

OECD concluded that there was no scientific basis for specific legislation, and the recommendations included the harmonization of approaches through the sharing of information and experience by member countries while protecting intellectual property.

Recommendations specific for industry included that large-scale industrial application of rDNA techniques should preferably utilize organisms that are intrinsically of low risk and that are handled under conditions of Good Industrial Large-Scale Practice (GILSP). Measures of containment, in addition to GILSP, were advocated when an assessment of risk (according to criteria contained in the report) indicated the need for additional precautions.

Recommendations specific for environmental and agricultural applications stressed the importance of careful evaluation of rDNA organisms for potential risk and the precaution of proceeding in a step-wise fashion, e.g. from laboratory to growth chamber to greenhouse to limited field testing and finally to large-scale field testing.

II THE UNITED KINGDOM

The requirements of the *Health and Safety at Work Act 1974* cover biotechnology, including rDNA techniques. The Health and Safety (Genetic Manipulation) Regulations 1978 require notification to the Health and Safety Executive of

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* Note: this information is selective rather than comprehensive.

intention to carry out genetic manipulation, as defined in the regulations, and the provision of details of individual experiments. There is also a non-mandatory notification scheme for large-scale use (fermentation at 10 litres or more) of genetically manipulated organisms. The legislation was expected to be strengthened (August 1, 1989) by the incorporation of voluntary guidelines into law.

Detailed guidelines for genetic manipulation were drawn up by the former Genetic Manipulation Advisory Group (GMAG) and its successor body, the Advisory Committee on Genetic Manipulation (ACGM). The committee advises the Health and Safety Commission, the Health and Safety Executive and government departments, where necessary. The guidance provided indicates how to achieve the right balance between the level of risk and the cost of containment under the general requirements of the *Health and Safety at Work Act 1974*.

In June 1988 the Advisory Committee on Genetic Manipulation produced two documents: "Guidelines for the Categorisation of Genetic Manipulation Experiments" (ACGM/HSE/Note 7) and "Laboratory Containment Facilities for Genetic Manipulation" (ACGM/HSE/Note 8). Both documents supersede earlier documents prepared by the GMAG.

The Department of the Environment released a consultation paper in June 1989: "Environmental Protection: proposals for additional legislation on the intentional release of genetically manipulated organisms"(GMOs). Four main elements were proposed:

1. a general duty of care to protect the environment on those releasing GMOs
2. notification to ministers by those proposing to release GMOs
3. authorization by ministers of proposed releases
4. appropriate enforcement of the provisions.

The responses to this document are to provide the basis for legislation that is to be introduced in November 1989.

The Royal Commission on Environmental Pollution issued its thirteenth report on July 6, 1989: "The Release of Genetically Engineered Organisms to the Environment". Some recommendations of the royal commission are reflected in the consultation paper mentioned previously. A new framework for regulation was suggested within which the Secretary of State for the Environment and the Health and Safety Commission would act jointly to protect human health and the environment.

In the agricultural context, biotechnology is covered by guidelines as well as by numerous pieces of legislation.

III EUROPEAN COMMUNITY DIRECTIVES

In March 1988 the Commission of the European Communities approved a regulatory framework for the use of genetically modified organisms. There were two directives in the proposed legislation.

The first related to applications of biotechnology in contained systems and was limited to micro-organisms. It required the assessment of the genetically modified organism against a set of criteria and the establishment of working practices and/or containment in proportion to the hazard. A system of notification was proposed to allow monitoring (see summary in Table 5.1).

In June 1989 The Environmental Council reached political agreement on a revised version of the directive and changed the legal basis. The European Commission has reserved the right to ask the Court of Justice for an opinion. The revisions to the notification procedure are set out in Table 5.2 and are more rigorous than previously proposed. The directive includes definitions for "micro-organism", "genetically-modified micro-organism" and "contained use".

NOTIFICATION FOR THE CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS
EUROPEAN COMMUNITY

Table 5.1

As proposed 1988

	LOW VOLUME (RESEARCH)	HIGH VOLUME DEVELOPMENT & PRODUCTION
GROUP 1 ORGANISMS (MINIMAL RISK)	**RECORD OF WORK** Available to government on request	**PRIOR NOTIFICATION OF WORK** Work may proceed immediately after notification
GROUP 2 ORGANISMS (HIGH OR UNKNOWN RISK)	**PRIOR NOTIFICATION** 15–day waiting period	**PRIOR NOTIFICATION & SAFETY ASSESSMENT** 60–day waiting period

Table 5.2

As agreed by the Environmental Council June 1989

	TYPE A OPERATIONS E.g. teaching, research, development or non–industrial and non–commercial ends	TYPE B OPERATIONS All other operations
TYPE 1 ORGANISMS (LOW RISK)	**RECORD OF WORK** Initial users to give notification Users to keep register of work to be available to competent authorities	**PRIOR NOTIFICATION OF WORK** Initial users to notifiy and await authorization Users to notify with a 60 day waiting period
TYPE 2 ORGANISMS (HIGH RISK)	**PRIOR NOTIFICATION** Users to notify with a 60 day waiting period	**PRIOR NOTIFICATION & SAFETY ASSESSMENT** Users to notify and await written authorization; decision to be given within 90 days

The second directive covered all operations involving the intentional introduction into the environment of a genetically modified organism at any stage from research to product marketing. Case-by-case notification, genetic and ecological assessment and endorsement procedures are called for; see Table 6 for summary information. Agreement was not reached on this directive, which is to be discussed further in September 1989.

Table 6

NOTIFICATION FOR THE DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS

	FIRST MEMBER STATE	COMMISSION & OTHER MEMBER STATES
RESEARCH (limited and scaled up field trials)	NOTIFICATION, 90-day waiting period, ENDORSEMENT by the competent authority	RECEIVE summary of notification, MAY SUGGEST modifications to conditions of use
PRODUCT MARKETING	NOTIFICATION, 90-day waiting period for response by the competent authority	RECEIVE summary of notification MAY OBJECT within 60 days, ENDORSEMENT BECOMES FINAL if no objection

IV NEW ZEALAND

In July 1988 the Ministry for the Environment published a discussion document, "New Organisms in New Zealand: Procedures and Legislation for the Importation of New Organisms into New Zealand and the Development, Field Testing and Release of Genetically Modified Organisms". The framework proposed in the document includes notification, assessment, the granting of permits and post-importation monitoring. The right of the public to be informed and to comment is emphasized.

V THE UNITED STATES OF AMERICA

The National Institutes of Health (NIH) published the latest version of the NIH "Guidelines for Research Involving Recombinant DNA Molecules" in 1986 (*Federal Register* Vol 51, 18958); these guidelines were in addition to the recommendations for the safe use of infectious agents contained in "Biosafety in Microbiological and Biomedical Laboratories", published by the Centers for Disease Control and NIH.

In June 1986 the Office of Science and Technology Policy published a notice in the *Federal Register* (Vol 51, 23302) entitled "Co-ordinated Framework for Regulation of Biotechnology". This described the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and invited public comment.

At the same time, the Department of Agriculture (USDA) published a proposed rule, "Plant Pests; Introduction of Organisms and Products Altered or Produced Through Genetic Engineering" (*Federal Register*; Vol 51, 23351) and an "Advanced Notice of Proposed Guidelines for Biotechnology Research" (*Federal Register*; Vol 51, 23367). Regarding the latter, the agency is to publish a notice in the *Federal Register* that will contain research guidance consisting of a general guideline, principles and a handbook of procedures for field testing biotechnology-modified organisms; adherence to the guidelines and handbook will be made a condition of accepting USDA research funds (*Federal Register*; Vol 53, 41730, 1988).

Currently, the Environmental Protection Agency (EPA) is proceeding with rulemaking relating to "biotechnology" under the authority of the *Toxic Substances Control Act (TSCA)*. The agency is proposing two separate regulatory actions for manufacturers, importers and processors of certain microbial products of biotechnology. It is planned that there will be notification prior to testing new micro-organisms in the environment and a special mechanism for experimental releases (see *Unified Agenda, Federal Register*; Vol 54, paragraph 2844 1989).

Under section 5, EPA proposes to amend the definition of "small quantities solely for research and development" to require notices prior to testing new micro-organisms in the environment. This will require reporting for new micro-organisms and will establish a special notification mechanism for experimental releases of micro-organisms.

Also proposed are significant new-use notification requirements under section 5 (a)(2), which would ensure that EPA would receive for review, notices of large-scale releases of other micro-organisms developed for significant new uses and review small-scale environmental releases, possibly with assistance from environmental biosafety committees, peer review committees to be sponsored by researchers and accredited by EPA.

EPA published two notices (*Federal Register*; Vol 54, 7026-7) in February 1989:

1 Under the heading "Biotechnology; request for comment on regulatory approach", EPA solicited comment on the direction of its program under TSCA to ensure that products of biotechnology are tested, manufactured, processed and used in a manner that does not present an unreasonable risk of injury to human health or the environment.

2 Under the heading "Microbial Pesticides; request for comment on regulatory approach", EPA invited comments on issues that had arisen in the development of an amendment to its Experimental Use Permit (EUP) regulations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The amendment would require prior notification before initiation of small-scale testing of certain genetically modified microbial pesticides, and a determination whether an EUP would be required. It is intended to provide sufficient oversight of the early testing of these microbial pesticides to mitigate any adverse human health or environmental effects.

APPENDIX 5

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Labour (chair)
Agriculture and Food
Environment
Health
Industry, Trade and Technology
Natural Resources
Treasury and Economics

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